EXHIBIT J

In the Matter Of:

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY

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EXHIBIT NO. 759

Federal And State Role in Pharmacy Compounding and Reconstitution: Exploring The Right Mix To Protect Patients

Hearing before the U.S. Senate Committee on Health, Education, Labor, and Pensions

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Mr. Chairman and Members of the Committee, thank you for the opportunity to speak with you today about the serious public health implications of pharmacy compounding—a topic which has been the focus of my professional practice and research for the past 8 years.

I am a licensed pharmacist with a specialization in sterile compounding. I have served as a member of the FDA's Advisory Committee on Pharmacy Compounding—a committee established to assist with the implementation of Federal pharmacy compounding regulations under the 1997 FDA Modernization Act. I am currently completing my Master of Public Health degree at Johns Hopkins Bloomberg School of Public Health, with a focus on pharmacoepidemiology and drug safety within the Department of Health Policy and Management.

More recently, I have established a small non-profit organization to study, analyze and communicate drug safety issues to concerned stakeholders.

I have survived two cancers and have lived with chronic rheumatic disease since my early childhood. I have come to rely on the exceptional quality of federally regulated pharmaceuticals from both a personal and professional perspective—the basic assurances to public health and safety provided by the Federal Food, Drug, and Cosmetic Act, that all citizens rely on, should not be undermined.

Over a decade ago, I began my career as a community pharmacist with a homecare pharmacy that provided injections to patients for administration in their homes. The pharmacy was making purportedly sterile injections from scratch using non-sterile ingredients. When I asked permission to order and substitute FDA-approved products because of safety concerns, I was cautioned that it would be less profitable for the pharmacy. At that time, a sterile drug for continuous intraspinal infusion had an acquisition cost of approximately $400.00. However, using non-sterile, raw chemical ingredients the drug could be made for less than $10.00. Although Medicare reimbursed close to $1,000.00 for the drug at the time under Medicare Part B, profits could be maximized by making the drugs from scratch. The compounded dosage forms did not undergo a validated sterilization procedure, were not tested for potency or purity, and the risks of using such a product were not identified, analyzed or communicated to physicians or their patients. This emerging practice concerned me for both medical and ethical reasons—patients were unknowingly exposed to drugs that did not meet strict Federal standards for safety and efficacy, manufacturing or

labeling to ensure safe use. I quickly learned that my experience was not unique—the practice was becoming "standard of care" in certain medical settings.

In 1998 I was appointed to the FDA's Advisory Committee on Pharmacy Compounding. During the implementation process, a group of compounding pharmacies challenged advertising restrictions in the new law, which led to a U.S. Supreme Court ruling that ultimately resulted in the nullification of Section 503a of FDA Modernization Act and the return of pre-FDAMA enforcement discretion on the part of the FDA. The absence of Federal compounding regulations has created vulnerabilities in our gold standard system for pharmaceutical regulation. Currently, compounding regulations are disparate and minimally enforced at the State level. Moreover, FDA simply does not have the information or resources to track down violative pharmacy compounding operations.

What is Traditional Pharmacy Compounding?

On a practical level, pharmacists are trained during their tenure in pharmacy school to convert tablets to liquids and to make topical formulations to meet exceptional medical needs that cannot be met with approved products. For instance, a 2-year-old transplant patient may require an anti-rejection medication that is only available in tablet form. In such a case, the tablet may be reformulated into an oral liquid for administration—such a medication would be considered life-sustaining and the expected benefits would likely outweigh risks associated with the use of an unlicensed product.

What is Contemporary Pharmacy Compounding?

Contemporary pharmacy compounding represents an emerging, substandard drug industry that exploits the traditional role of compounding by taking advantage of current loopholes in the law and resource constraints with regulators. The industry is supported and driven by profiteering distributors that supply chemicals (including active and inactive ingredients), equipment (including industrial size mixers, capsule and tablet machines), recipes, training and marketing tools for compounding pharmacists. This has resulted in the emergence and growth of a substandard industry of unregulated drug manufacturing, marketing, promotion and sales throughout the U.S. Recently, Reuters Health reported an estimate of 3,000-4,000 compounding pharmacies nationwide [2], some of which dispense over 100 unregulated, compounded prescriptions per day. In some instances, compounding pharmacies have begun to attempt the tactics of mainstream drug manufacturers, and are seeking to employ sales representatives that would detail doctors about the availability and supposed benefits of their products.

What Are the Benefits and Risks of Contemporary Pharmacy Compounding?

The claimed benefits of contemporary compounding include creating patient specific and individualized dosage forms to meet any dosing requirement; providing varying strengths, sizes and shapes, dye-free, preservative free, and lactose free dosage forms; providing custom flavoring, and the provision of unavailable, unformulated and discontinued items; and providing increases in profitability for pharmacies and medical practices. Such benefits are broadly marketed through advertisements over the Internet, directly to physicians through professional detailing, and through the media. But such advertisements do not meet Federal requirements for presenting balanced information on risks. Pharmacists, through such advertisements, misuse the public trust in pharmacy and place patients and prescribers at a significant disadvantage for selecting safe and

effective treatments. Physicians have come to expect products to be uniform in quality and may not appreciate the risks that are enhanced or created with compounded agents [3].

The full range of risks associated with the use of compounded drugs have not been identified, analyzed or communicated to patients or prescribers. Section 502(n) of the FD&C Act requires that a manufacturer include a summary of risks in advertising—all materials and statements, including press materials, oral statements, and sales materials for managed care organizations and hospitals must meet FDA requirements for truthfulness, fair balance and full disclosure [6]. Compounded drugs do not meet such requirements—promotional information for drugs made by pharmacists is devoid of risk information.

The true benefits of contemporary compounding may be financial. In a recent Medicare fraud case involving the mass manufacturing of adulterated and misbranded respiratory drugs an underlying reason for compounding was explained by a witness who said "it is cheaper to make a compound solution and sell this medication than to buy an industrial product from an authorized supplier, it is much more expensive, so the profit you are going to obtain with a brand is much less than the one you are going to obtain with compounding. That is the reason for compounding, it is only profit." [7] In an article examining the acquisition cost of respiratory drugs which appeared in the homecare trade journal HME News, a compounding supplier noted that "providers, especially small ones, will risk compounding before losing that kind of money" and further acknowledged that "it's illegal, but profitability often overrules what's legal and illegal." [8] The article further notes that compounding would be difficult to detect because of how Medicare is billed "Hence, there's no way for the FDA to know whether a provider is using the premixed drug or compounding the two drugs themselves." The financial incentives to compound drugs raise serious concerns regarding conflict of interest for compounding pharmacists who promote their use. If physician self-referral is constrained under the Stark laws, so too should compounding pharmacist self referral be penalized and restrained. In a debate appearing in the Journal of the American Academy of Child and Adolescent Psychiatry, physicians disputed the rationale for compounded hormone treatments for use in adolescent patients and questioned the proprietary interests of compounding pharmacists who promoted their use [9-11].

What Are the Public Health Implications of Contemporary Pharmacy Compounding?

In 1996, former FDA Commissioner David Kessler, MD warned that exempting pharmacy compounding from provisions of the Food, Drug, and Cosmetic Act would create a shadow industry of unapproved drug manufacturing thus undermining the FDA's authority to protect the public from ineffective or unsafe products [12].

Compounded drugs are produced outside our Federal regulatory framework and carry risks of subpotency, superpotency and/or contamination. Complete and unbiased information on the size and scope of the industry has not been generated—we cannot estimate with accuracy the exposures of patients to unapproved, pharmacy made drugs and the associated effects on morbidity and mortality.

The ability of States to adequately protect the public from substandard drug exposure may be confounded by discrepant, over-lapping and in some cases non-existent State regulations, a lack of resources and lack of will. Professional standards for sterile compounding have not been consistently applied [14,15], and newly introduced, enforceable standards issued by the United States Pharmacopeia are optional for State boards to adopt and enforce [15].

Pharmacists Are Drug Experts, Not Manufacturing Experts

A recent letter to the American Journal of Health System Pharmacists noted that pharmacy curricula do not give attention to sterile compounding procedures, and that this deficit is more pronounced in the U.S. than in Europe [16] Pharmacists who compound drugs may not understand the complex system of drug regulations that provide public health protections. For instance, a pharmacist may not know that a raw bulk chemical that has been manufactured for use in an oral dosage form may not meet specifications for use by the intravenous or intraspinal route of administration. Pharmacists may generalize that a particular filter will sterilize any solution, independent of the properties of the solution or potential adulterants present. John Perrin Ph.D., professor emeritus from the University of Florida confirms that "Technology has been downplayed in pharmacy schools for the last 25 years; we are not training pharmacists to make value judgments on what can and cannot be compounded and yet compounding is the fastest growing branch of the profession." [17] Indeed, a compounding pharmacy advertises "No longer are you limited to 'standard' medicine. Your choices now include new routes of administration, dosage strengths, pharmaceutical combinations and the ability to develop new, potentially helpful compounds. Medicine can be as large as your imagination." [18] In other words, if a physician can imagine it, a compounding pharmacist can make it—without prior approval for safety or efficacy, without adherence to current Good Manufacturing Practices and without adhering to labeling, marketing or advertising requirements.

Analyses of Compounded Drugs

How well do pharmacists exact specific dosages? A recent study of prescription dispensing errors found that pharmacy compounding errors had significantly more serious outcomes and that children are "particularly at risk because of the increased potential for error in the preparation and use of liquids." [19] Such concerns have been heightened by a recent FDA survey of compounded drugs which found a 34 percent failure rate for drugs analyzed for potency and/or purity—of those drugs that failed potency tests, more than half contained less than 70 percent of their labeled content [20] An analysis of a pharmacy-compounded remedy for treating ulcer disease concluded that the mixture was not stable and would undergo hydrolysis rendering it partially inactive immediately after mixing [21]. Other published reports and studies have found super and sub-potency, unacceptable levels of microbial contamination and the presence of impurities in pharmacy-compounded drug products [22,23]. Of great concern, as of today over a million doses of pharmacy-compounded drug products distributed throughout the U.S. have been recalled for bacterial or fungal contamination [24, 25]. These risks of pathologic contamination are particularly disturbing when one considers that the compounding industry targets respiratory and parenteral routes of administration, and particularly to the home care market which largely serves a vulnerable and immunocompromised elderly population.

Quality of Chemicals Used in Compounding

The quality of raw bulk chemicals used in compounding is suspect. Pharmacists generally do not have the ability to test chemicals for identity, potency, purity and/or contamination. Because the 1987 Prescription Drug Marketing Act's Pedigree Requirements have not been implemented, the ability to trace the raw chemicals used in compounding back to original manufacturers for information on quality, packaging, storage and shipment conditions is demonstrably difficult.

A 2000 hearing before the House E&C Committee chaired by the Honorable Fred Upton cited compounding pharmacies as a primary route of entry for counterfeit bulk drugs. "Lured by high

prices and potential profits in the U.S., counterfeit bulks can get into our prescription drugs in several ways: (1) as imported ingredients to U.S. manufacturers; (2) as imported ingredients to pharmaceutical compounders; and (3) as source ingredients for Internet pharmacies marketing to the U.S. The counterfeiters use sophisticated methods such as preparing false labeling, containers, seals and certificates of analysis, or using a manufacturing process that differs from the filed manufacturing process." [26] This problem has also been recognized by authorities in Canada—a notice was recently sent to pharmacies alerting pharmacists that non-compliant, raw bulk chemicals were being offered for sale to pharmacies for compounding [27]. A letter from the Commerce Committee requesting information from former FDA Commissioner Jane Henney, MD which preceded the hearing, cautioned that counterfeit bulk drugs: "pose a real or potential health hazard because their manufacturer is often unknown" [28] and that the "impurity profile is [also] unknown, and the age, the storage, the manufacturing environment, or the synthesis of the product cannot be determined" [28], creating a situation where "no amount of finished product testing can build quality into the product." [28] In the U.S., although surveillance is limited, large quantities of chemicals for use in compounding have been recalled because bulk drug packages contained the wrong chemical ingredient, and for potential contamination or failed purity tests [29].

Compounding pharmacists have also expressed concerns regarding the quality of bulk chemicals available for compounding. A Kansas City, Missouri compounding pharmacy's website notes that "inexpensive chemicals that are past or near expiration, with no independent verification, are available, but unacceptable to O'Brien Pharmacy." [30] The same pharmacy however, has marketed a narcotic morphine sulfate injection for intraspinal administration that exceeds the physical solubility for the chemical under normal storage conditions [31].

At Risk Populations

Certain patient populations may be exposed to unapproved, compounded drugs more than others. Marketing and advertising for compounded drugs targets special populations including pediatric patients for which reflavoring is often suggested to make medicines more palatable, respiratory care patients who require treatments with nebulizers, elderly patients and hospice patients who may require alternate dosage forms, women to whom specialized hormone treatments are marketed, and men for sexual dysfunction treatments. Compounded drugs are also marketed directly to physicians' offices to improve profit margins for providing in-office injections.

Much attention has been focused on the long term safety of hormone replacement treatments—recent epidemiologic studies have found increased risks for certain cancers. This new risk information is now communicated to prescribers and patients for weighing therapeutic options and in order to manage risks. Compounding pharmacies are using this new information to promote alternative, unapproved hormone treatments—a compounding pharmacy claimed: "Women are no longer willing to accept the risks associated with synthetic hormones, and are searching for safer alternatives. An estimated two million women are now benefiting from natural 'plant-derived bio-identical' estrogens and progesterone." [32] There is no scientific substantiation for such claims. In fact, the hormone treatments marketed by compounding pharmacies may share similar or even greater risks—women are unknowingly receiving unproven, experimental therapies that may harm them in the absence of informed consent.

Adverse Events

The use of unregulated, pharmacy-compounded dosage forms has been associated with morbidity and mortality throughout the nation:

- An outbreak of bacterial meningitis in California was associated with compounded spinal injections—three patients died and eight were hospitalized.
- CDC warned physicians and health systems to consider substandard, compounded drug exposures in cases of unexplained infections following intraspinal or intra-articular injections after an outbreak of fungal meningitis was associated with compounded drugs—CDC further cautioned that health systems may not be aware that they are purchasing compounded drugs, thus actually requiring vigilance to prevent compounded drugs from inadvertently entering supply chains.
- Compounded spinal injections were associated with neurologic complications including paralysis in an epidemiologic cohort study of patients who received unapproved, pharmacy-compounded continuous intrathecal infusions [23].
- Three cases of poisonings in children have been associated with unapproved drugs compounded for Attention Deficit Hyperactivity Disorder [35,36].
- A 5-year-old died as a direct result of receiving an unapproved compounded drug for bed-wetting [37].
- Two patients developed septicemia and were hospitalized after receiving compounded vitamin injections contaminated with bacteria [38].
- Three patients were hospitalized in critical condition after receiving compounded thyroid remedies [39].
- A cancer patient died after receiving a compounded injection of herbal tea [40].
- A patient became blind after using compounded eye-drops that were not sterile [20].
- A study comparing a compounded prostaglandin dosage form with a licensed product found a higher incidence of cesarean delivery associated with the compounded drug [41].
- An estimated 4,000 cancer patients received diluted, sub- therapeutic chemotherapeutic agents compounded in Missouri [31].

The above mentioned cases are considered the "tip of the iceberg" by public health experts because pharmacists, unlike licensed manufacturers, are not required to detect or report problems associated with compounded drugs they make. These problems have come to the attention of the public only when the numbers of persons affected by a single incident or the severity of an incident have been significant enough to gain the attention of the media—not through surveillance and vigilance.

Surveillance

Compounded drugs are hard to trace making it difficult to measure or assess overall efficacy and safety. A 1998 report in Drug Topics examined 285 clonidine poisonings that were reported to the Kentucky Regional Poison Center during a 6-year period. Clonidine was primarily prescribed for ADHD with the largest demographic age group of 1-3 years (99 children) [42]. Because a pediatric dosage form for clonidine did not exist, much of what was being administered was likely compounded. Of serious concern, pharmacy compounded, sustained-release clonidine dosage forms have been marketed to prescribers—a physician's practical guide states: "it has been recommended to substitute the usual nighttime clonidine dosing with a pharmacy-compounded clonidine sustained release form, made by compounding clonidine with a hydroxyl-propylmethylcellulose extended-release polymer or with guanfacine." [43] The erratic and unpredictable release from a pharmacy-compounded, purportedly sustained-release dosage form or from simple calculation errors may contribute to observed cases of clonidine toxicity—such dosage forms have not been tested to confirm extended-release and pharmacokinetic profiles. Three cases appearing in the medical literature have associated pharmacy-compounded clonidine preparations with clonidine poisonings in children [35-36], but such associations are difficult to

make without adequate surveillance.

Cost

Pharmacists make more money when they dispense unapproved, compounded formulations [44]. The average gross profit for a compounded prescription is estimated at $31.50 based on 1998 figures. According to Thomas Kaye RPh, MBA with Blue Cross Blue Shield of Oklahoma, the frequency of prescribing and reimbursement claims for compounded drugs has been increasing for many plans in recent years—he cautions that incidents associated with the use of such unapproved products "add to overall patient cost, as well as morbidity and mortality." [45]

State Oversight

State Boards of Pharmacy oversight of pharmacy compounding is discrepant and regulations are minimally enforced. While some States have adopted compounding rules that provide some public health protections, other States permit unrestricted distribution of compounded drugs that are not dispensed pursuant to an authorized, unsolicited prescription.

New Federal Regulations Are Necessary

It is ironic that so much concern is currently focused on the importation of drugs from other countries that may not match our gold standard system of regulation for pharmaceuticals, while we have within our own borders a flourishing, unregulated drug industry that manufactures, markets, and sells substandard products throughout the U.S.

If we do not act in the interest of public health and safety now, the history of substandard drug exposures and the related morbidity and mortality that led to the Kefauver-Harris Drug Amendments of 1962 will be relived through contemporary pharmacy compounding.

Recommendations To Protect the Public From the Hidden Risks of Unregulated, Pharmacy Compounded Drugs

- Disclosure to prescribers and patients that compounded drugs are not FDA-approved and consumers should be advised of alternative FDA approved products.
- Disclaimer on all compounded drug containers: THIS DRUG HAS NOT BEEN TESTED OR REVIEWED BY THE FOOD AND DRUG ADMINISTRATION (FDA) FOR SAFETY OR EFFECTIVENESS AND HAS NOT BEEN PRODUCED IN A FACILITY MEETING GOOD MANUFACTURING PRACTICES GUIDELINES.
- Requirement that prescribers be notified before a compounded product is dispensed.
- Prohibition against the compounding of drugs too difficult to compound for safety reasons.
- Strict pedigree requirements for all chemicals used in compounding.

Summary of Testimony

- Pharmacy-compounded drugs do not meet Federal requirements for establishing safety and efficacy (21 U.S.C. § 355), for manufacturing (21 U.S.C. § 351(a)(2)(b)) or labeling for safe use (21 U.S.C. § 352(0(1)).
- Accurate, complete and unbiased information about the size and scope of the compounding industry in the U.S. is not available.

- Federal compounding regulations (1997 FDA Modernization Act Section 503a) were nullified through a U.S. Supreme Court ruling in 2002. Current State compounding regulations are inadequate to protect public health and safety and to prevent individual patient exposures to unacceptable risks.
- Lack of oversight of the compounding industry has created avenues to introduce commercial quantities of unapproved drugs into the market place through wholesale transactions [1]
- Morbidity and mortality associated with compounded drugs has been observed but because pharmacists are not required to detect or report problems associated with drugs they compound, the known cases of deaths, injuries, exposures and recalls of dangerous products are considered "tip of the iceberg" by public health officials [20, 23, 31, 33-41].
- To address this issue, Senator's Bond and Roberts have offered an amendment to the Senate version of the Prescription Drug and Medicare Improvement bill (S. 1) to establish an advisory committee within the FDA to examine whether patients are receiving necessary, safe, and accurate dosages of compounded drugs. This is a critical first step in examining the public health risks associated with this newly emerging industry.
- New Federal legislation for pharmacy compounding is necessary to protect patients and preserve the integrity of our Federal system of regulation for drug approval, manufacturing, and safety.

References

1. Department of Health and Human Services Food and Drug Administration warning letter to Unique Pharmaceuticals, October 10, 2001.
2. Pallarito, Karen. Legal-FDA ban on ads for drug compounding violates free speech. Reuters Health 2-14-2001.
3. Bouts, B. The Misuse of Compounding by Pharmacists. Quackwatch, accessed 08/01/02.
4. IACP Letter to Missouri State Board of Pharmacy Re: Proposed Rule 4 CSR 220-2.200 Sterile Pharmaceuticals, January 31, 2003.
5. Johnson PE. Legal and practice concerns with extemporaneously compounded medications. Journal of Pharmaceutical Care in Pain & Symptom Control 1997; 5(3):47-57.
6. Pina, Kenneth R. and Pines, Wayne L., Ed. A Practical Guide to Food and Drug Law and Regulation. Washington, D.C. Food and Drug Law Institute, 1998.
7. United States v. Idania Arias et al., Case No. 00-683-CR-LENARD. United States District Court, Southern District of Florida.
8. Beaulieu E. Duoneb pricing spells trouble for HMEs. HME News July 2001 accessed 7/23/02.
9. Schaller JL, Briggs B, Briggs M. Progesterone organogel for premenstrual dysphoric disorder. J Am Acad Child and Adolesc Psychiatry 2001; 39(3):261.
10. Bashford RA, Horrigan JP. Comment by Drs. Bashford and Horrigan, at the invitation of the editor on Progesterone organogel for premenstrual dysphoric disorder. J Am Acad Child and Adolesc Psychiatry 2001; 39(3):261.
11. Capps S. Progesterone organogel for premenstrual dysphoric disorder. J Am Acad Child and Adolesc Psychiatry 2001; 40(3):261.
12. Fairfax RA. "Phederalism": The Regulation of Pharmacy Compounding and Two Years in the Regulatory Turf War Between Pharmacy and the Food and Drug Administration, accessed 10/21/03.
13. American Pharmaceutical Association—About Importing Medications and Internet Pharmacies. Importing Medications: Getting Your Questions Answered. Accessed 10/19/03.
14. Trissel L. Compounding our problems—again. Am J Health-Syst Pharm 2003 Mar; 60:432.

15. Thompson C. USP publishes enforceable chapter on sterile compounding. Am J Health-Syst Pharm 2003; Sept 60:1814-17.
16. Sabra K. Standards for pharmacy compounding. Am J Health-Syst Pharm 2003; Sept 60:18141817.
17. Perrin JH. Comments on drugs difficult to compound and the quality of chemicals used in compounding. Drug Development and Industrial Pharmacy 1999; 25(4):553-57.
18. McGuff Compounding Services, Inc. Explanation of Compounding Pharmacy and What to Look for in a Compounding Pharmacy. Accessed 10/ 19/03.
19. Seifert SA. Pharmacy prescription errors reported to a regional poison control center. Journal of Toxicology CLINICAL TOXICOLOGY 2002; 40(7):919-23.
20. Subramaniam V, Sokol G, and Zenger V et al. Survey of drug products compounded by a group of community pharmacies: Findings from an Food and Drug Administration study. Accessed 10/19/03.
21. Dansereau RJ, Lowe E, and Stella M. Alternative to bismetet available-A compounding formula presented for informational purposes only was found not to be stable by Proctor and Gamble researchers; a commercial alternative is described. American Druggist 1997:58.
22. Sarver JG et al. Analysis of extemporaneous alprostadil formulations. International Journal of Pharmaceutical Compounding 1999; 3(2):148-54.
23. Jones TF, Feler CA, Simmons BP et al. Neurologic complications including paralysis after a medication error involving implanted intrathecal catheters. The American Journal of Medicine 2002; 112(1):31-36.
24. FDA Enforcement Reports accessed 10/13/03: October 16, 2002 Portage Pharmacy; April 9, 2003 Lee Pharmacy; February 12, 2003 Urgent Care Pharmacy; March 27, 2002 Med-Mart Pulmonary Services .
25. Missouri Department of Economic Development News Release. Missouri Board of Pharmacy takes action against Kansas City Company. March 10, 2003.
26. Prepared Statement of the Honorable Fred Upton before the House Commerce Committee Subcommittee on Oversight & Investigations Subject—Counterfeit Bulk Drugs. June 8, 2000.
27. National Association of Pharmacy Regulatory Authorities. Health Canada Notice March 7, 2003.
28. The Honorable Tom Bliley, chairman, The Committee on Commerce. United States House of Representatives Letter to The Honorable Jane Henney, M.d. May 8, 2000.
29. FDA Enforcement Reports: Medisca Pharmaceutique April 23, 2003; Hawkins Chemical August 15, 2000; Paddock Labs March 15, 2000; Professional Compounding Centers of America August 19, 1992 .
30. O'Brien Pharmacy Quality Assurance Procedure. Accessed 10/13/03.
31. Morris M and McGuire D. Three-Part Special Report: Rx for disaster: Some pharmacists who mix medicines dispense unsafe drugs. The Kansas City Star October 6-8, 2002.
32. South River Compounding Pharmacy. Accessed 12/27/02.
33. Russell S and Hallissy E. Chronicle Investigation: Who's mixing your drugs? Bad medicine: Pharmacy mix-ups a recipe for disaster. San Francisco Chronicle June 23, 2002.
34. Centers for Disease Control. Exophiala Infection from contaminated injectable steroids prepared by a compounding pharmacy—United States, July-November 2002. MMWR December 13, 2002/51(49);1109-1112.
35. Suchard JR and Graeme KA. Pediatric clonidine poisoning as a result of pharmacy compounding error. Pediatric Emergency Care 2002 18(4):295-96.
36. Ramano MJ and Dinh A. (2001) A 1000-fold overdose of clonidine caused by a compounding error in a 5-year-old child with ADHD. Pediatrics 108(2):471-72.
37. 37, Glod M. Pharmacist penalized in death of boy, 5; Va. Board rules in medication error.

The Washington Post. August 17, 2000.
38. Department of Health and Human Services Food and Drug Administration warning letter to College Pharmacy, April 7, 1999.
39. Teegardin C, Probe questions safety of pharmacy-made drugs. The Atlanta Journal—Constitution Friday March 30, 2001.
40. Hartman T. Springs pharmacy sued in injected tea death. The Gazette April 11, 1999.
41. Sanchez-Ramos L, Farah LA, and Kaunitz AM et al. Preinduction cervical ripening with commercially available prostaglandin E2 gel: a randomized, double-blind comparison with a hospital compounded preparation. Am J Obstet Gynecol 1995; 173(4):1079-84.
42. Gebhart, Fred (1998) Clonidine implicated in household poisonings. Drug Topics, Nov 2:27.
43. Oesterheld A, Tervo R. (1996). Clonidine: a practical guide for usage in children. South Dakota Journal of Medicine: 234.
44. Coyne PJ, Hansen LA, Watson AC. Compounded Drugs: Are customized prescription drugs a salvation, snake oil or both? American Journal of Nursing 2003; 103(5) 78-85.
45. Kaye T. The quandary of compounding for MCOS: Administrative costs, risks, and waste. Managed Care 2003: 42-8.
46. Department of Health and Human Services Food and Drug Administration warning letter to Carneys Drug May 27, 2003.
47. Department of Health and Human Services Food and Drug Administration warning letter to Med-Mart Pulmonary Services September 30, 2002.
48. American Society of Health-System Pharmacists Board of Directors. ASHP Report ASHP Guidelines on managing drug product shortages. Am J Health-Syst Pharm 2001; 58:14451450.
49. Harlow S. Missouri officials begin tracking contaminated drug. The Kansas City Star March 13, 2003.
50. Erickson SJ, Duncan A. Clonidine poisoning: an emerging problem: epidemiology, clinical features, management and prevention strategies. J Paediatr Child Health 1998; 34:280-82.

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